

## REMARKS

Claims 1-3, 8, 11, 12, 14, 15 and 17-28 are pending in the present application.

It is believed these changes do not involve any introduction of new matter. Consequently, entry of these changes is believed to be in order and is respectfully requested.

### Rejections Under 35 USC §103(a) Over Bhat et al. (WO 96/25913) in view of Gavin et al (WO01/00151)

Claims 1-3, 8, 11, 12, 14, 15 and 17-28 remain rejected under 35 USC §103(a) as being unpatentable over Bhat et al. (WO 96/25913) in view of Gavin et al (WO01/00151). Applicants respectfully traverse this rejection.

The Office Action asserts Bhat et al. teaches compositions comprising monophasic zinc hydroxycarbonate as antimicrobial agent in personal care products, such as shampoos, wherein there is a synergistic action of zinc hydroxycarbonate with detergent and/or anti-dandruff actives like zinc pyrithione in shampoos/hair dressings. The Office Action thus asserts that the art has already established compositions comprising zinc hydroxycarbonate and zinc pyrithione in personal care products.

The Office Action further asserts that the difference between the instant application and Bhat et al. is that Bhat et al. do not expressly teach the amount of zinc pyrithione present, the various 'augmentation factors'; or gallery ions in the zinc containing layered material. The Office Action asserts that this deficiency in Bhat et al. is cured by the teachings of Gavin et al. The Office Action further asserts that the difference between the instant application and Bhat et al. is that Bhat et al. does not expressly teach a methods for preparing a personal care composition by reacting in a personal care composition comprising zinc pyrithione a carbonate or bicarbonate with a zinc compound, wherein the molar ratio is between about 1:10 and about 10:1; and wherein the zinc pyrithione and the basic zinc carbonate are simultaneously or step

wise generated. The Office Action asserts that this deficiency in Bhat et al. is cured by the teachings of Gavin et al. The Office Action further asserts the difference between the instant applications and Bhat et al. is that Bhat et al. do not expressly teach a method of treating microbial or fungal infections. The Office Action asserts that this deficiency is cured by the teachings of Gavin et al. Applicants respectfully traverse these assertions.

The Office Action further asserts, in response to the Applicant arguments filed May 25, 2010, as well as the Declaration under 37 CFR 1.132 from James R. Schwartz dated May 25, 2010, the Office Action asserts that the Applicant has amended the Claims to be directed to an impurity containing hydroxy-containing basic zinc carbonate and has argued that Bhat et al. teaches a pure basic zinc carbonate without impurity. The Office Action further asserts that Applicant has asserted that the monophasic zinc hydroxycarbonate of Bhat et al. is without any other impurity phases and whereas in contrast the basic zinc carbonate materials of the claimed invention (e.g. from Bruggemann) are composed of more than one phase (i.e. is not monophasic) and are thus multi-phasic. The Office Action asserts that while this is a clever argument there are several faults with this line of reasoning. First, the Office Action asserts that the instant claims *are not drawn to multi-phasic basic zinc carbonate*. However, Applicants assert that as described by Bhat et al., hydrozincite (naturally occurring) and basic zinc carbonate are equivalent names for zinc hydroxycarbonate (Page 1, lines 23-24 and line 35). The term “*monophasic*” is defined (Page 1, lines 29-33) as “*without any other impurity phases ... present ...*”. In contrast, the present invention, as amended, is further defined as an impurity containing hydroxy-containing basic zinc carbonate. Support for the amendment is found in the specification at page 5, lines 19-21 -- The idealized stoichiometry is represented by  $Zn_5(OH)_6(CO_3)_2$  but the actual stoichiometric ratios can vary slightly and *other impurities may be incorporated* in the crystal lattice. Therefore, Applicant amended the claim language commensurate with the specification. Further, monophasic is defined in Bhat et al. as “without any other impurities” and the simple selection of the term “multi-phasic” (i.e. is not monophasic) in the filed response of May 25, 2010, is synonymous with “impurity containing” as claimed in

the present invention. Further, the claimed invention does not comprise a monophasic, or “without any other impurity phases” zinc hydroxycarbonate as defined by Bhat et al.

In further response to the Applicants arguments filed May 25, 2010, the Office Action asserts that the difference in zinc lability of Bruggemann (56.9%) and Elementis (51.6%) is merely a *difference in degree* and *not a difference in kind*. The Office Action asserts that they are *essentially equivalent*. The Office Action further asserts that the crystallite size of the Bruggemann sample (103 Angstroms) is *only slightly less* than the crystallite size of the Elementis sample (134 Angstroms) and both possess *nearly the same* relative zinc lability (56.9% and 51.6%) respectively. The Office action asserts that it can only conclude that there is no significant difference between these two samples as multi- or mono-phasic does not appear to make any difference in the resulting relative lability. Applicants respectfully traverse these two assertions. Applicants further submit a Declaration under 37 CFR 1.132 from James R. Schwartz in support against the present Office Action assertions.

In the 1.132 Declaration submitted herein, to establish the impact that changes in zinc lability of basic zinc carbonate materials has on efficacy, an *In Vivo* Malassezia Automated Counting (IMAC) data from a study was correlated to the measured zinc lability values of various basic zinc carbonate materials found in the present invention and further discussed in the previous filed 1.132 Declaration of May 25, 2010.

Data from the *In Vivo* Malassezia Automated Counting (IMAC) method measures the ability of an anti-dandruff product to reduce the population of Malassezia yeast on the scalp. There is a very strong relationship between reduction in Malassezia levels and resultant clinical efficacy (reduction in flake symptoms). Thus IMAC Malassezia reduction is a proxy measurement for anti-dandruff efficacy.

In this IMAC Study, shampoo prototypes that differed only in the source of the basic zinc carbonate were evaluated for *in vivo* Malassezia reduction capability. This data is tabulated in the 1.132 Declaration in comparison to the zinc lability data for basic zinc carbonate materials of different origin and disclosed in the present invention, namely Bruggemann, Elementis, and

Cater. Bruggemann is an “impurity containing” basic zinc carbonate, wherein Elementis and Cater are more *without any other impurity* phases or monophasic. As demonstrated in the Table 1 and Graph 1 of the 1.132 Declaration, there is a significant reduction in Malassezia count for Bruggemann at 251.2 when compared to Cater at 155.7 and Elementis at 214.1. The data indicates a strong correlation between zinc lability and product efficacy, as expected from the mechanistic understanding: zinc lability is a measure of the ability of a material to release zinc ions, which are the source of the augmentation benefit.

A basic zinc carbonate *without any other impurity* phases or monophasic, such as those from Elementis and Cater, do not possess the same efficacy as an impurity containing basic zinc carbonate, such as Bruggemann as evidenced by the supporting data in the 1.132 Declaration.

There is no motivation to combine the teaching of Bhat et al. with Gavin et al. and arrive at the claimed invention, as neither Bhat et al. nor Gavin et al. disclose an impurity containing hydroxy-containing basic zinc carbonate. Accordingly, the rejection is untenable and should be withdrawn.

35 USC §103

Applicants would like to note the following, as further found in the Office Action at Page 2:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Applicants highlight, for emphasis purposes, that the above patent statute states -- the prior art are such that the subject matter *as a whole* would have been obvious at the time the invention--.

In the prosecution of the present application, Applicants note that in the present office action, the rejections under 35 USC §103(a) is Over Bhat et al. (WO 96/25913) in view of Gavin et al (WO01/00151). In the Office Action mailed on 04/27/2007, Claims 1-4, 8, 9, 11, 12, 14-17 and 23-25 were rejected under 35 USC §103(a) Over Gavin et al (WO01/00151) in view of Bhat et al. (WO 96/25913). Applicant filed subsequent amendments and arguments against the above rejection (Gavin et al (WO01/00151) in view of Bhat et al. (WO 96/25913) on 10/23/07.

In a subsequent office action mailed on 03/04/2009, at page 2, under “Withdrawn rejections” it states that “Applicant’s amendments and arguments filed 10/23/07 and 2/14/08 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed below is herein withdrawn. Applicant’s amendments and arguments have overcome the rejections of record and those rejections are withdrawn by the Examiner.” From this statement, the Applicant’s amendments and arguments filed on 10/23/07 which were in response to the above rejection (Gavin et al (WO01/00151) in view of Bhat et al. (WO 96/25913) have overcome this rejection of record and this rejection is withdrawn by the Examiner.

However, in a subsequent Office Action mailed on 11/25/09, Claims 1-3, 8, 11, 12, 14, 15 and 17-28 were rejected under 35 USC §103(a) Over Bhat et al. (WO 96/25913) in view of

Gavin et al (WO01/00151) and this rejection has been maintained in further Office Actions mailed on 5/25/10 and 8/17/10. This new rejection appears misplaced in view of the earlier withdrawal of the claim rejection over identical art.

Applicants assert that they have successfully overcome wherein “the prior art are such that the subject matter *as a whole* would have been obvious at the time the invention”. Applicants successfully overcame the 35 USC §103(a) rejection of Gavin et al (WO01/00151) in view of Bhat et al. (WO 96/25913). Therefore, the subject matter of the present invention as a whole is not obvious in view of Gavin et al (WO01/00151) in view of Bhat et al. (WO 96/25913). And the re-ordering of this art rejection, wherein the rejection is USC §103(a) Over Bhat et al. (WO 96/25913) in view of Gavin et al (WO01/00151) is inconsistent. The subject matter of the present invention *as a whole* has been found to be not obvious in view of Gavin et al (WO01/00151) in view of Bhat et al. (WO 96/25913) and once this finding has been established, it is inconsistent to further find that the subject matter of the present invention *as a*

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*whole* is now obvious in view of Bhat et al. (WO 96/25913) in view of Gavin et al (WO01/00151). Applicants have overcome the rejection of this prior art and the Office Action of 03/04/09 has withdrawn this rejection. Therefore, the subject matter of the present invention as a whole has been previously found to be not obvious in view of either Gavin et al (WO01/00151) in view of Bhat et al. (WO 96/25913) and such should be considered not obvious in view of Bhat et al. (WO 96/25913) in view of Gavin et al. Applicants respectfully request reconsideration and withdraw of this rejection.

#### Conclusion

This response represents an earnest effort to place the application in proper form and to distinguish the invention as now claimed from the applied references. In view of the foregoing, reconsideration of this application, entry of the amendments presented herein, and allowance of Claims 1-3, 8, 11, 12, 14, 15 and 17-28 is requested.

Respectfully submitted,  
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